

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
<b>THIS DOCUMENT RELATES TO: ETHICON WAVE 5 CASES</b>	

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO  
EXCLUDE CERTAIN OPINIONS OF RAGNVALD MJANGER, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response in opposition to Plaintiff's Motion to Exclude Certain Opinions of Ragnvald Mjanger, M.D. *See* Doc. 4414 and 4415.

**INTRODUCTION**

Dr. Mjanger is an obstetrician and gynecologist focusing on treating incontinence, prolapse and other pelvic floor disorders. Doc 4414-3, Ex. C. to Pls.' Motion, Expert Report at 1. He has been board-certified in obstetrics and gynecology since 2000 and Female Pelvic Medicine and Reconstructive Surgery since 2015. *Id.* at 1 and Doc 4414-2, Ex. B to Pls.' Motion, Mjanger CV at 1. Dr. Mjanger is a clinician, in private practice in St. Paul, Minnesota and an Assistant Clinical Professor at the University of Minnesota Medical School. *Id.*

Dr. Mjanger has performed over 10,000 pelvic surgeries including many different types of procedures to treat stress incontinence, including open and laparoscopic retropubic urethropexies, Burch and Marshall-Marchetti-Krantz (MMK) procedures, needle suspensions, fascial bladder neck slings, and synthetic mid-urethral slings. Doc. 4414-3, Pls. Motion, Ex. C, Expert Report at 1. He has also taught other physicians how to perform these procedures. *Id.*

Dr. Mjanger also performs revision procedures. Doc. 4414-4, Pls.' Motion, Ex. D, 7/20/17  
Mjanger Dep. at 60:11-21.

In these cases, Dr. Mjanger intends to offer opinions generally addressing the utility and safety of the TVT and TVT-O devices. His opinions are based upon his education, medical training, clinical experience, review of medical literature, position statements, guidelines, curricula, and various other materials reflected in his reliance list. Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 1-2; Ex. A hereto, Reliance List. Although Plaintiffs have challenged certain aspects of Dr. Mjanger's opinions, as set forth below, he is qualified to opine on these topics and his opinions are supported by a reliable methodology. Plaintiffs' arguments lack merit and should be denied.

### **ARGUMENT**

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

#### **I. Dr. Mjanger is qualified to testify regarding the adequacy of the warnings.**

Dr. Mjanger has opined on the adequacy of the TVT and TVT-O IFU warnings from a clinical perspective based on his knowledge of and clinical experience with the devices. *E.g.*, Doc. 4414-3, Pls.' Motion. Ex. C, Expert Report at 2, 12-13. Plaintiffs do not challenge, or even address, Dr. Mjanger's clinical expertise. Instead Plaintiffs argue that he is not qualified to opine on the adequacy of the IFUs because he lacks familiarity with the regulatory process governing the development of such documents.

Ethicon concedes that Dr. Mjanger is not a regulatory expert and will not opine on warnings from that perspective. Consistent with the Court's prior rulings as to other urogynecologist expert witnesses [Dr. Flynn], however, Dr. Mjanger, as an Ob/Gyn and female pelvic medicine and reconstructive specialist, "he may testify about the specific risks of

implanting mesh and whether those risks appeared on the relevant IFU.” *In re: Ethicon*, 2016 WL 4582231, at \*3 (S.D. W. Va. Aug 31, 2016). Dr. Mjanger’s report details his experience with the TVT and TVT-O devices, including particular risks and complications he has experienced. Doc. 4414-3, Pls.’ Motion. Ex. C, Expert Report at 12-13. His extensive clinical experience with the products at issue is supplemented by a thorough review of the relevant literature, his education and training, including education he has provided to others. *Id.*, Ex. A hereto, Reliance List; Doc. 4414-2, Pls.’ Motion Ex. B, Mjanger CV.

Plaintiffs do not appear to challenge Dr. Mjanger’s competency to testify that risks that did not appear on the IFUs were already commonly known to clinicians but to the extent that their motion is construed to do so, any such challenge should be denied. Dr. Mjanger will testify that the complications that Plaintiffs allege should have been in the IFUs: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device. Doc. 4414-4, Pls.’ Motion Ex. D, 7/20/17 Mjanger Dep. at 283-285, 288.

As it relates to the latter two categories, Dr. Mjanger’s report shows that his opinions are based on his extensive clinical experience, *as well as* his critique of scientific literature. *See, e.g.*, Doc. 4414-3, Pls.’ Motion. Ex. C, Expert Report at 8-10. (explaining why he disputes that mesh causes various conditions, such as damage from contraction, cytotoxicity, or degradation); *see also Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of

absence because his opinions were also based on medical literature); *Carlson*, 2015 WL 1931311 at \*12 (S.D. W. Va. Apr. 28, 2015).<sup>1</sup>

Dr. Mjanger, as an experienced clinician, is well qualified to testify about complications that are commonly known such that they need not be included in an IFU. Doc. 4414-3, Pls.’ Motion. Ex. C, Expert Report at 12-13. The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) Tort: Product Liability §2 cmt. J. (1988); Restatement (Second) of Law of Torts §402A cmt. J.; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4<sup>th</sup> Cir. 1990). In fact, 21 CFR §801.109(c) states there is no duty to warn if “the article is a device for which the hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Experts may testify as to the knowledge common within a profession or community. *See Flannery v. Bauermeister*, No. CIV. A. 06-399S, 2008 WL 77723, at \*2 (D. R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from defendants’ experts as to what “is known within the correctional medical community”); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1<sup>st</sup> Cir. 2003) (allowing expert testimony of “common knowledge”); *U.S. v. Articles of Device*, 426 F.

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<sup>1</sup> While this Court has observed that “[a]bsence of evidence is not evidence of absence,” *Tyree*, 54 F. Supp. 3d 501, 583-84 (S.D. W. Va. 2014), the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where, as here, a physician examines the evidence outside of his own experience, such as by critiquing the medical literature and studying the conclusions of medical organizations, then the physician’s opinions have a reliable basis. If there is no reliable evidence of risk as determined by a detailed review of appropriate sources, there is no obligation to include the risk in the IFU warnings.

Supp. 366 (W.D. Pa. 1977) (FDA offered affidavit in misbranding case). Thus, the TVT and TVT-O IFUs supplement all of the other sources of a surgeon's knowledge.

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Mjanger is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how an average clinician would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Mjanger. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFU failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

**II. Dr. Mjanger is qualified to render opinions regarding the utility and safety of the TVT and TVT-O devices, and his opinions are supported by reliable methodology**

Plaintiffs claim that Dr. Mjanger "should be precluded from giving design opinions" on the basis that he has inadequate expertise with the design process and product development. Doc. 4415, Pls.' Motion at 7. As set forth below, Dr. Mjanger does not intend to provide design process opinions, and he is well qualified to testify about the safety and utility of the devices.

**A. Dr. Mjanger will not provide design process opinions**

Plaintiffs made this same challenge as part of their motions to exclude other defense expert opinions in Wave 1 cases. Noting that Plaintiffs' motion was "plagued with confusion about what constitutes a design opinion," the Court correctly found that "[Dr. Woods] has not expressed any opinions about the process of designing a product." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582231, at \*3 (S.D. W. Va. Sept. 1, 2016). Therefore, the Court denied Plaintiffs' challenge to the defense experts design opinions "as moot". *Id.*

The Court should make the same finding in this Wave of cases. Dr. Mjanger does not intend to opine about product design and development, and Plaintiff's motion should not be construed as challenging Dr. Mjanger's opinions about the safety and efficacy of TVT or TVT-O.

**B. Ethicon's internal product design process documents are irrelevant to Dr. Mjanger's safety and utility opinions.**

Relying exclusively on this Court's opinion in *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222 (S.D. W. Va. Apr. 24, 2015), Plaintiffs argue that because Dr. Mjanger has not reviewed Ethicon's internal documents about its design process, he cannot opine about any issues that touch upon product design. As previously noted by Ethicon, Dr. Mjanger does not intend to offer *any* opinion regarding the adequacy of Ethicon's internal design procedures or Ethicon's compliance with industry standards during the development of the devices. To the extent that Plaintiffs seek to use Dr. Mjanger's failure to review certain design process documents as a basis to exclude his opinions about the safety and efficacy of TVT and/or TVT-O, Plaintiffs' motion lacks merit and should be denied.

This Court's decision in *Winebarger* lends no support to Plaintiffs' argument. In that case, Boston Scientific challenged the opinion of the plaintiff's proposed expert, Dr. Bobby Shull, regarding Boston Scientific's failure to "follow its own internal protocols" and its "lack of due diligence in the design and development" of the product in issue. *Winebarger*, at \*14. Dr. Shull, however, did not review any documents related to Boston Scientific's standard operating procedures or its design protocols. *Id.* Consequently, this Court held that "[w]ithout any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures for the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

In contrast to Dr. Shull in *Winebarger*, Dr. Mjanger does not intend to offer any opinions regarding Ethicon’s “internal design procedures,” and therefore, it was unnecessary for Dr. Mjanger to review any of Ethicon’s internal documents related to design procedures. In fact, in *Winebarger*, the Court allowed Dr. Patrick Culligan, a defense expert urogynecologist, to opine about the safety and efficacy of the medical device, even though the Court concluded that Dr. Culligan was not competent to testify about mesh design. *Id.* at \*33-35. This Court has found that other physicians with surgical experience were competent to offer opinions similar to that of Dr. Mjanger. *See, e.g., Tyree*, 54 F. Supp. 3d at 550; *Jones v. Bard, Inc.*, No. 2:11-cv-00114 [Doc. 291], pp. 6-9; *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at \*33 (S.D. W. Va. Apr. 28, 2016).

Plaintiffs have chosen to focus on an opinion Dr. Mjanger has not offered related to documents Dr. Mjanger was not even asked to review. Quite simply, Plaintiffs have not shown and cannot show that a review of Ethicon’s internal product design process documents was necessary for any of the opinions that Dr. Mjanger intends to provide in these cases.

**C. The complication and satisfaction rates in Dr. Mjanger’s practice are consistent with the rates reported in the peer-reviewed medical literature.**

Plaintiffs argue that Dr. Mjanger should be precluded from opining on the design of the TVT and TVT-O “being reasonably safe” because he relies “solely on his personal experience using the products and not the design protocols or methodology of a medical device manufacturer.” Doc. 4415, Pls. Motion at 9-10. Ethicon acknowledges that, in its Wave 1 rulings, the Court excluded expert witness opinions regarding complication rates in an expert’s own practice on the basis that “his complication rates derive entirely from mental estimates and not from accumulated data or patient records.” *In re: Ethicon*, 2016 WL 4582231, at \*3. Ethicon respectfully suggests that Dr. Mjanger’s opinions about these rates in his own practice

are sufficiently reliable and that the Court allow Dr. Mjanger to testify about such rates consistent with other decisions issued by the Court. *See Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S. D. W. Va. Nov. 20, 2014) (“If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions”); *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at \*34 (S.D. W. Va. Apr. 24, 2015) (finding that expert’s inability to provide “exact statistics” about the outcome of his patients did not render his personal experience opinions unreliable and that “such detail is not required under *Daubert* to opine as to ‘large-scale’ safety and efficacy of the Uphold device”); *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at \*33 (S.D. W. Va. Apr. 28, 2016) (same).

Alternatively, the Court, as it did in its Wave 1 rulings, should limit its exclusion of Dr. Mjanger’s opinions to his statements about his own patient’s outcomes. To the extent that Plaintiff’s motion could be construed as challenging Dr. Mjanger’s ability to provide opinions about the safety and efficacy of TVT and TVT-O beyond his own personal experience, it should be denied.

Indeed, Dr. Mjanger’s extensive personal experience, coupled with his reliance on medical literature, make him well-qualified to opine about the safety and utility of the devices. Dr. Mjanger is a skilled female pelvic floor surgeon with over 25 years of experience treating stress urinary incontinence and female pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. Doc. 4414-3, Pls.’ Motion. Ex. C, Expert Report at 1. He has implanted thousands of TVT and TVT-O devices and regularly treats patients for complications related to pelvic surgery. *Id.*; Doc. 4414-2, Pls.’ Motion Ex. B, Mjanger CV.



As reflected in his report, and supported by published studies, the rate of mesh exposure for TVT ranges on average from 1- 3% in the peer reviewed literature. E Doc. 4414-3, Pls.’ Motion. Ex. C, Expert Report at 6-8; Doc. 4414-4, Pls.’ Motion Ex. D, 7/20/17 Mjanger Dep. at 279-282. Dr. Mjanger believes his personal success and complication rates to be generally consistent with the peer-reviewed scientific literature. Doc. 4414-4, Pls. Motion Ex. D, 7/20/17 Mjanger Dep. at 279-282.

### **III. Dr. Mjanger is competent to testify about degradation.**

As this Court concluded in its rulings in Wave 1 as to Plaintiff’s argument that another expert witness [Dr. Flynn] was not competent to testify about degradation was “without merit.” *In re: Ethicon*, 2016 WL 4556807, at \*4 (S.D. W. Va. Aug. 31, 2016). The Court held that Dr. Flynn’s “extensive clinical experience, combined with [his] review of the scientific literature, qualifies [him] to opine on mesh’s reaction to and effect on the human body.” *Id.* The same analysis should apply to Dr. Mjanger.

Dr. Mjanger’s opinions are particularly bolstered by his review of Level 1 long-term studies, RCTs, systematic reviews, meta-analyses, and Cochrane reviews demonstrating the safety of polypropylene mesh and that the mesh is not degrading. *See, e.g.*, E Doc. 4414-3, Pls.’ Motion. Ex. C, Expert Report at 6-10; Doc. 4414-4, Pl’s Motion Ex. D, 7/20/17 Mjanger Dep. at 289-290. As stated in Dr. Mjanger’s report, “Clinical evidence, including my own clinical experience, established that TVT mesh does not degrade in vivo. If it does, any such degradation does not (find any possible testimony that would work here about his personal experience and any literature testimony). Doc. 4414-3, Pls.’ Motion. Ex. C, Expert Report at 9.

Plaintiffs fault Dr. Mjanger for not reviewing the devices’ design history files, but Dr. Mjanger does not offer opinions about Ethicon’s process of developing products. Indeed,

Dr. Mjanger's opinions about degradation are not at the molecular level and the equivalent of the opinions of a polymer scientist, but instead, are focused on clinical aspects of alleged degradation. *See Wilkerson*, 2015 WL 2087048, at \*20 (S.D. W. Va. May 5, 2015). ("That he [Dr. Porter] has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about 'what's happening at the molecular level'").

Plaintiffs also argue that Dr. Mjanger should not be allowed to testify about the lack of any meaningful clinical effects of degradation, because he "does not hold himself out as an expert in chemical engineering, pathology, or polymer chemistry."; "has not done any bench or lab research on polypropylene or polypropylene meshes"; "has never performed any kind of pathological analysis on any explanted polypropylene meshes and . . . is not a biomaterials specialist." Pl's Motion at 11. In *Huskey*, this Court rejected a similar challenge to defense expert urogynecologist, Harry Johnson, M.D. 29 F. Supp. 3d at 735. Noting that although "Dr. Johnson's opinion is not subject to testing and it is not supported by peer-reviewed literature *affirmatively* stating that degradation lacks clinical significance," Dr. Johnson's "clinical experience and his review of the scientific literature" set forth a sufficient basis for his opinion and "Dr. Johnson's failure to review particular documents goes to the weight of his opinion, not its admissibility." *Id.* Again, "[i]f there are certain device-specific publications that [Plaintiffs claim that Dr. Flynn] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Trevino*, 2016 WL 2939521, at \*41.

#### **IV. Dr. Mjanger's opinions regarding safety and efficacy of the TVT and TVT-O are based in sound methodology.**

Dr. Mjanger has applied a sound methodology in formulating his opinions regarding the safety and efficacy of TVT and TVT-O and the rates referenced in his testimony are supported by his thorough review of peer-reviewed publications demonstrating the long-term safety of the

devices, as well as the repeated endorsement of medical societies. Doc. 4414-4, Pls.' Motion Ex. D, 7/20/17 Mjanger Dep. at 279-282. His opinions are also supported by his decades of clinical experience and medical training. Although Dr. Mjanger could not verify precise percentages for specific types of complications realized in his practice, that failure does not impact his ability to testify about the safety and efficacy of TVT and TVT-O, as demonstrated by the scientific literature that he has reviewed.

This Court has recognized that a physician may testify that complication rates found in literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert applied reliable methodology supporting opinion that product was safe and effective where opinion was based upon "minimal complications in his clinical practice" which was "on par with the findings of [the] studies' he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at \*12, \*36 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine how these procedures compare.) That is precisely what Dr. Mjanger will do in these cases. Any alleged inconsistencies or weaknesses in Dr. Mjanger's testimony go to its weight, not its admissibility. *See Daubert*, 509 U.S. 579, 596 (1993) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attaching shaky but admissible evidence.")

## CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to exclude Dr. Mjanger's testimony.

Dated: August 29, 2017.

Respectfully submitted,

NILAN JOHNSON LEWIS PA

By: /s/ Tracy J. Van Steenburgh

Tracy J. Van Steenburgh

Reg. No. 141173

**Nilan Johnson Lewis PA**

120 South Sixth Street, Suite 400

Minneapolis, MN 55402-4501

Telephone: (612) 305-7500

Facsimile: (612) 305-7501

[tv@nilanjohnson.com](mailto:tv@nilanjohnson.com)

Christy D. Jones

**Butler Snow LLP**

1020 Highland Colony Parkway

Suite 1400 (39157)

P.O. Box 6010

Ridgeland, MS 39158-6010

(601) 985-4523

[christy.jones@butlersnow.com](mailto:christy.jones@butlersnow.com)

David B. Thomas (W.Va. Bar #3731)

**Thomas Combs & Spann PLLC**

300 Summers Street

Suite 1380 (25301)

P.O. Box 3824

Charleston, WV 25338

(304) 414-1807

[dthomas@tcspllc.com](mailto:dthomas@tcspllc.com)

**COUNSEL FOR DEFENDANTS**

**ETHICON, INC. AND JOHNSON & JOHNSON**

### **CERTIFICATE OF SERVICE**

I hereby certify that on August 29, 2017 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Tracy J. Van Steenburgh  
Tracy J. Van Steenburgh

# EXHIBIT A

# **Ragnvald Mjanger**

## **Reliance List** ***in Addition to Materials Referenced in Report***

## Medical Literature

Agostini A, et al. [Pop 12,280] Immediate complications of tension-free vaginal tape (TVT): results of a French survey. Eur J Obstet Gynecol. 2006; 124:237-239.
Aigmuller T, et al. [10 yr fu] Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol. 2011; 205:496.e1-5.
Albo M, Richter, Zimmern, Moalli, Sirls. - NEJM - SISTEr study - Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Engl J Med 2007;356:2143-55.
Amid PK. Biomaterials for abdominal wall hernia surgery and principles of their applications. Langenbecks Arch Chir (1994) 379:168-171
Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia:1997;1:15-21.
Angioli R, Plotti F, Muzii L, Montera R, Panici PB, Zullo MA. Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomised trial. Eur Urol 2010;58:671-677.
Boukerro. Objective analysis of mechanical resistance of tension-free devices. European Journal of Obstetrics & Gynecology and Reproductive Biology 124 (2006) 240-245
Boukerrou M, et al. Study of the biomechanical properties of synthetic mesh implanted in vivo. Eur J Obstet Gynecol Reprod Biol (2007) 134:262-267
Brubaker L, et al. Adverse events over two years after retropubic or transobturator midurethral sling surger: Findings from the trial of midurethral slings (TOMUS) Study. Am J Obstet Gynecol 2011;205:498e.1-6
Cassidenti A. The crushing of innovation for treating female pelvic floor disorders: A Story of "Lead or be Led." OBG Management 2016; 28(4): 9-14
Celebi - [Pop 563, 5 yrs fu] Results of the TVT procedure for treatment of female SUI: a 5 year follow-up study; Arch Gynecol Obstet (2009) 279:463-467
Collinet P. et al. The Safety of the Inside-Out Transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women. Int Urogynecol J (2008) 19:711-715
Costantini. [Pop 87, median 100 mos fu] Long-term efficacy of the trans-obturator and retropubic MUS for SUI: update from a randomized clinical trial; World J Urol, DOI 10.1007/s00345-015-1651-z, 2015
Cox A, Herschorn S, Lee L. [Nat Rev Urol] Surgical management of female SUI: is there a gold standard? Nat Rev Urol. 2013 Feb;10(2):78-89.
Cresswell J, et al. [pop 118, mean 6.6 yrs fu] Long-term evaluation of tension-free vaginal tape (TVT) outcomes for a UK Surgeon: Objective assessment and patient satisfaction questionnaires. British Journal of Medical and Surgical Urology (2008) 1, 58-62.
Dietz HP, et al. [Pop 68, median 1.6 yrs fu] Does the Tension-Free Vaginal tape stay Where you Put It? Am J Obstet Gynecol 2003; 188:950-3
Dietz HP, et al. Mechanical properties of urogynecologic implant materials. Int Urogynecol J (2003) 14:239-243.
Drutz H. IUGA guidelines for training in female pelvic medicine and reconstructive pelvic surgery (FPM-RPS). Updated Guildelines 2010. Int Urogynecol K=J 2010; 21: 1445-1453.
Dyrkorn OA, Kulseng-Hanssen S, Sandvik L. TVT compared with TVT-O and TOT: Results from the Norwegian National Incontinence Registry; Int Urogynecol J (2010) 21:1321-1326.
Falconer C. Clinical Outcome and Changes in Connective Tissue Metabolism After Intravaginal Slingplasty in Stress Incontinence Women. Int Urogynecol J 1996; 7: 133-137
Ford AA, et al. (Cochrane Review[FULL]) Mid-urethral sling operations for stress urinary incontinence in women. The Cochrane Library 2015, Issue 7
Groutz A, Rosen G, Cohen A, Gold R, Lessing JB, Gordon D. [Pop 52, 10 yr fu] Ten-year subjective outcome results of the retropubic tension-free vaginal tape for treatment of stress urinary incontinence. J Minim Invasive Gynecol (2011) 18:726-729



## Medical Literature

Han J-Y, Park J, Choo M-S. [Pop 88, 12 yr fu] Long-term durability, functional outcomes, and factors associated with surgical failure of tension-free vaginal tape procedure. <i>Int Urol Nephrol</i> (2014) 46:1921-1927
Hansen, Gradel. [Danish Registry] Reoperation for urinary incontinence-a nationwide cohort study, 1998 thru 2007; <i>Am J Obstet Gynecol</i> 2016;214:263.e1-8
Heinonen P. [Pop 191, mean 10.5 yrs fu] Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome. <i>Int J Urol</i> 2012; 19:1003-1009
Holmgren S, Nilsson. [Pop 760, 8 yr fu] Long-Term Results with Tension-Free Vaginal Tape on Mixed and Stress Urinary Incontinence. <i>Obstetrics &amp; Gynecology</i> ; Vol. 106, No. 1, July 2005
Jelovsek J, et al. [Pop 72, mean 62 mos fu] Randomized trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. <i>BJOG</i> 2008; 115: 219-225.
Jonsson Funk M. Sling Revision/ Removal for Mesh Erosion and Urinary Retention: Long-Term Risk and Predictors. <i>Am J Obstet Gynecol.</i> 2013; 208(1): 73.e1-73.e7
Karlovsy M. Synthetic Biomaterials for Pelvic Floor Reconstruction. <i>Current Urology Report</i> 2005; 6:376-384
Kenton K, Zyczynski H, Sirls LT, Richter HE, et al. (TOMUS published) 5-Year Longitudinal Followup after Retropubic and Transobturator Mid-urethral slings. <i>The Journal of Urology</i> , Vol. 193, 203-210, January 2015.
Kersey J. The gauze hammock sling operation in the treatment of stress incontinence. <i>British Journal of Obstetrics &amp; Gynecology</i> 1983; 90:945-949.
Kirby A. Midurethral slings: which should I choose and what is the evidence for use? <i>Curr Opin Obstet Gynecol</i> 2015; 27: 359-365
Kuuva N, Nilsson. [Pop 1455, 2 mo fu] A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. <i>Acta Obstet Gynecol Scand</i> 2002; 81: 72-77
Laurikainen E, Valpas A, Aukee P, Kivelä A, Rinne K, Takala T, Nilsson CG. [Pop 254, 5 yr fu] Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. <i>Eur Urol</i> (2014) 65:1109-1114
Li B, Zhu L, Lang JH, Fan R, et al. [Pop 55, 7 yr fu] Long-term outcomes of the tension-free vaginal tape procedure for female stress urinary incontinence: 7-year follow-up in China. <i>J Minim Invasive Gynecol.</i> 2012 Mar-Apr;19(2):201-5.
Liapis A, Bakas P, Creatsas G. [Pop 65, 5 & 7 yr fu] Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. <i>Int Urogynecol J Pelvic Floor Dysfunct</i> (2008) 19:1509-1512
Lo TS, et al. Ultrasound assessment of mid-urethra tape at three-year follow-up after tension-free vaginal tape procedure. <i>Urology</i> 63:671-675, 2004
Lukacz ES, et al. [Pop 54, 1 yr fu] The effects of the tension-free vaginal tape on proximal urethral position: a prospective, longitudinal evaluation. <i>Int Urogynecol J Pelvic Floor Dysfunct.</i> 2003 Aug;14(3):179-84.
Moalli PA, et al. Tensile Properties of five commonly used mid-urethral slings relative to the TVT. <i>Int Urogynecol J</i> (2008) 19:655-663.
Moir J. The Gauze-Hammock Operation. A Modified Aldrige Sling Procedure. <i>The Journal of Obstetrics and Gynaecology of the British Commonwealth</i> Vol. 75, No. 1 January 1968
Nager C. Midurethral Slings: Evidence-based Medicine vs. The Medicolegal System. Accepted Manuscript to appear in: <i>American Journal of Obstetrics and Gynecology</i> ; 2016 doi: 10.1016/j.ajog.2016.04.018
Nager C. Midurethral Slings: Evidence-Based Medicine vs. The Medicolegal System. <i>American Journal of Obstetrics and Gynecology</i> 2016 DOI: 10.1016/j.ajog.2016.04.018
Nguyen J. [Pop 4,142] Perioperative Complications and Reoperations After Incontinence and Prolapse Surgeries Using Prosthetic Implants, <i>Obstet Gynecol.</i> 2012 Mar;119(3):539-46

## Medical Literature

Nichols DH. The Mersilene Mesh Guaze-Hammock for Severe Urinary Stress Incontinence. <i>Obstet Gynecol</i> 1973; 41(1): 88-93.
Nilsson C. [7 yr fu] Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. <i>Obstet Gynecol</i> (2004) 104, 1259-1262
Nilsson C. Creating a gold standard surgical procedure: the development and implementation of TVT. <i>Int Urogynecol J</i> 2015; 26(4): 467-469
Nilsson C. Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary Incontinence. <i>Int Urogynecol J</i> 2001; (Suppl 2): S5-S8
Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C. [Pop 58, 17 yrs fu] Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. <i>Int Urogynecol J</i> (2013) 24: 1265-1269
Nilsson CG. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. <i>Int Urogynecol J</i> (2008) 19: 1043-1047
Nilsson M, et al. (Swedish Registry) [Pop 3334, 12 mo fu] Female urinary incontinence: patient-reported outcomes 1 year after midurethral sling operations. <i>Int Urogynecol J</i> . 2012 Oct;23(10):1353-1359.
Novara G, Galfano A, Boscolo-Berto R, Secco S, Cavalleri S, Ficarra V, Artibani W. [meta-analysis] Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. <i>Eur Urol</i> 53 (2008):288-309
Ogah. Minimally invasive synthetic suburethral sling operations. <i>Cochrane Review [Abstract] Cochrane Database Review; The Cochrane Library</i> 2009, Issue 4
Olsson I, Abrahamsson AK, Kroon UB. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. <i>Int Urogynecol J</i> (2010) 21:679-683
Pandit A. Design of surgical meshes - an engineering perspective. <i>Technology and Health Care</i> 2004; 12: 51-65
Petros P. Creating a gold standard surgical device. Scientific discoveries leading to TVT and beyond. <i>Int Urogynecol J</i> DOI 10.1007/s00192-015-2639-3
Prien-Larsen JC, Hemmingsen L. [Pop 316, 5 yr fu] Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene tape. <i>Int Urogynecol J Pelvic Floor Dysfunct</i> (2009) 20:703-709
Reich A, Kohorst F, Kreienberg R, Flock F. [7 yr fu] Long-term results of the tension-free vaginal tape procedure in an unselected group: a 7-year follow-up study. <i>Urology</i> (2011) 78:774-777
Richter, Brubaker, Zimmern, Sirls (UITN) SISTEr [Pop 482, 7 yr fu] Patient Related Factors Associates with Long-Term Urinary Continence After Burch Colposuspension and Pubovaginal Fascial Sling Surgeries. <i>J Uro</i> , Vol. 188, 485-489, August 2012
Schimpf MO, Rahn DD, Wheeler TL et al. (published) [meta-analysis] Sling surgery for stress urinary incontinence in women: a systematic review and meta-analysis. <i>Am J Obstet Gynecol</i> (2014) 211:71.e1-71.e27
Schiotz H. [Pop 33,10 yr fu] Ten-year follow-up after conservative treatment of stress urinary incontinence. <i>Int Urogynecol J</i> (2008) 19:911-915
Schraffordt Koops. [Pop 634, 2 yr fu] Quality of life before and after TVT, a prospective multicenter cohort study, results from the Netherlands TVT database; <i>BJOG</i> 2006; 113:26-29
Schraffordt Koops. The effectiveness of tension-free vaginal tape (TVT) and quality of life measured in women with previous urogynecologic surgery; Analysis from the Netherlands TVT database; <i>American Journal of Obstetrics and Gynecology</i> (2006) 195, 439-44

## Medical Literature

Serati M, Ghezzi F, Cattoni E, Braga A, Siesto G, Torella M, Cromi A, Vitobello D, Salvatore S. [Pop 58, but 10 yrs fu] Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up. <i>Eur Urol</i> (2012) 61:939-946
Shao U, et al. [Pop 24, median 57 mo fu] Tension-free vaginal tape retropubic sling for recurrent stress urinary incontinence after Burch colposuspension failure. <i>International Journal of Urology</i> (2011) 18, 452-457
Song PH, Kim YD, Kim HT, Lim HS, Hyun CH, Seo JH, Yoo ES, Park CH, Jung HC, Gomelsky A. [Pop 306, 7 yr fu] The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. <i>BJU Int.</i> 2009 Oct;104(8):1113-1117.
Song. [Pop 206, 13 yr fu] AUA Abs. MP33-03 The long-term outcomes from TVT procedure for female SUI; Data from minimal 13 years of follow up; <a href="http://www.aula2014.org">http://www.aula2014.org</a> 2014
Svenningsen R, et al. (Norwegian registry) [Pop 542, median 129 mo fu] Long-term follow-up of the retropubic tension-free vaginal tape procedure. <i>Int Urogynecol J.</i> 2013 Aug;24(8):1271-1278
Svenningsen R. [Pop 810, 10 yr fu] Risk Factors for Long-Term Failure of the Retropubic Tension-Free Vaginal Tape Procedure. <i>Neurourology and Urodynamics</i> (2013) 33:1140-1146
Tamussino K. (Austrian registry) [Pop 2543] Transobturator tapes for stress urinary incontinence: Results of the Austrian registry. <i>Am J Obstet Gynecol</i> 2007;197:634.e1-634.e5.
Tamussino KF, et al. Tension-free vaginal tape operation: Results of the Austrian Registry. <i>Obstet Gynecol</i> 2001; 98:732-736.
Thubert T. [Pop 98, 1 yr fu] Bladder injury and success rates following retropubic mid-urethral sling: TVT EXACT™ vs. TVT™ <i>European Journal of Obstetrics &amp; Gynecology and Reproductive Biology</i> 2016; 198: 78-83
Tincello. The TVT Worldwide Observational Registry for Long Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women; <i>The Journal of Urology</i> ; Vol. 186, 2310-2315, December 2011
Tommaselli GA, et al. Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. <i>Int Urogynecol J</i> (2015) DOI 10.1007/s00192-015-2645-5
Ulmsten U. A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence. <i>Int Urogynecol J</i> 1998; 9:210-213
Ulmsten U. An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence. <i>Int Urogynecol J</i> 1996; 7:81-86
Ulmsten U. Creating a gold standard surgical device: scientific discoveries leading to TVT and beyond. Ulf Ulmsten Memorial Lecture 2014. <i>Int Urogynecol</i> 2015; 26(6): 787-9
Ulmsten U. Intravaginal Slingplasty (IVS): An Ambulatory Surgical Procedure for treatment of Female Urinary Incontinence. <i>Scand J Urol Nephrol</i> 1995; 29:75-82
Unger CA, et al. [Pop 267] Indications and risk factors for midurethral sling revision. <i>Int Urogynecol J.</i> 2015; DOI:10.1007/s00192-015-2769-7.
Valpas, Nilsson. [Pop 121, 5 yr fu] TVT versus laparoscopic mesh colposuspension; 5 year follow-up results of a randomized clinical trial; <i>Int Urogynecol J</i> DOI (2014) 10.1007/s00192-014-2454-2
Ward K. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. <i>BJOG</i> 2008; 115: 226-233
Ward, Hilton. [Pop 344, 5 yr fu IRELAND study] TVT vs colposuspension for primary urodynamic stress incontinence: 5 year follow up. <i>Bjog</i> 2008; 115:226-233
Welk B. (Pop 60K) Removal or Revision of Vaginal Mesh used for the Treatment of Stress Urinary Incontinence. <i>JAMA Surg</i> (2015) Doi:10.1001/jamasurg.2015.2590
Williams TH, TeLinde RW. The Sling Operation for Urinary Incontinence Using Mersilene Ribbon. <i>Obstet Gynecol</i> 1962; 19(2):241-245.

**Medical Literature**

Young, Rosenblatt, et al. The Mersilene mesh suburethral sling: a clinical and urodynamic evaluation. AJOG 1995; 173:1719-1726.

**Production Materials**

<b>Document Description [Bates Range]</b>
A Solution-Gynecare TVT Tension-Free Support for Incontinence.
DEPO.ETH.MESH.00004755 - Guidoin Explant
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email string re - Revised write up of the DeLeval and Waltregny visit
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00349228 - Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device
ETH.MESH.00373310 - Gynecare TVT Tension-Free Support for Incontinence: General Profession Education Deck.
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation
ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh
ETH.MESH.00541379-80 - Mesh Fraying for TVT Devices
ETH.MESH.00575257 - Abbrevio laser cut vs. mechanically cut - notes from meeting with de leval - inappropriate
ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009
ETH.MESH.00584811-13 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT
ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09
ETH.MESH.00658177-198 - Surgeons Resource Monograph
ETH.MESH.00687819-22 - Email string re-Laser cut mesh
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858096-97 - Gynecare R&D Monthly Update - May
ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03
ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00870466 - Ethicon Expert Meeting-Meshes for Pelvic floor
ETH.MESH.00993273 - TVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.
ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009
ETH.MESH.01203957-97 - The future of surgical meshes-the industry's perspective
ETH.MESH.01219542-48 - Review of Surgeon Responses of VOC Questionnaire
ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings
ETH.MESH.01228079-84 - Nilsson Podcast Transcript
ETH.MESH.01238454-56 - Email string re-TVTO length
ETH.MESH.01279975-976 - Harel Gadot Email re Next step in SUI sling
ETH.MESH.01317508-613 - TVT Factbook DHF - Revised 05.14.2001
ETH.MESH.01752532-35 - Mesh design argumentation issues
ETH.MESH.01784823-28 - Clinical Expert report-Laser Cut Mesh
ETH.MESH.01785259-260 - Email string re: +M relaxation
ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TVT mesh
ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.
ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460



**Production Materials**

ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur October 18, 2006
ETH.MESH.01822361-62 - Dan Smith Email regarding TVT-Secur leading to less retention
ETH.MESH.02017152-56 - 02.23.2007 Ethicon Expert Meeting: Meshes for Pelvic Floor Repair
ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer
ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008
ETH.MESH.02211890 - Test Report
ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis
ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05)
ETH.MESH.02340568-90 - TVT-S IFU
ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05)
ETH.MESH.02341203-13 - TVT Abbrevo IFU
ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to 11.26.14)
ETH.MESH.03458123-38 - TVT Patient Brochure
ETH.MESH.03715978 - Weisberg email re: TVT question.
ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03907468-9 - Second Generation TVT - by Axel Arnaud
ETH.MESH.03910175 - Email string re - Soft Prolene
ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment
ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)
ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O
ETH.MESH.03916905-13 - Plaintiff's Exhibit 3827
ETH.MESH.03924557-86 - Meshes in Pelvic Floor Repair-Findings from literature review and conversations-interviews with surgeons, June 6, 2000.
ETH.MESH.03930120-123 - Nilsson C. Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol 2004; 104(6): 1259-62
ETH.MESH.03932909-911 - Confidential - History of TVT-O
ETH.MESH.03932912 - The History of TVT
ETH.MESH.03941623 - DeLeval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.04048515-520 - Carl Nilsson KOL Interview Project Scion 06.18.08
ETH.MESH.04081189 - Meeting Agenda
ETH.MESH.04082973 - Possible Complications for Surgeries to Correct POP and SUI
ETH.MESH.04092868 - Email re : 10100080654 and TVT IFUs
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevo
ETH.MESH.04941016 - Lightweight Mesh Developments (Powerpoint)
ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery
ETH.MESH.05479535
ETH.MESH.05588123-126 - Stephen Wohler Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05799233-39 - TVT Exact IFU
ETH.MESH.05918776 - Email re: Marlex Experience

**Production Materials**

ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Leval.
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA
ETH.MESH.06923868-71 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07226579-590 - 2000 - TVT CER
ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.08003181-96 - TVT Patient Brochure
ETH.MESH.08003231-46 - TVT Patient Brochure
ETH.MESH.08003279-94 - TVT Patient Brochure
ETH.MESH.08003295-302 - TVT Patient Brochure
ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08315779 - Clinical Expert report-09.25.2012
ETH.MESH.08334244; ETH.MESH.08334245 - Email re Photographs of LCM vs MCM with attachments
ETH.MESH.08334244-45 - Email string re-Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744858-63 - TVT Patient Brochure
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102
ETH.MESH.09922570-578 - R&D Memorandum of PA Mesh Assessments for TVTO-PA Revision 1
ETH.MESH.10281860 - Tension-Free Midurethral Sling: Market Update.
ETH.MESH.11336474-87 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report - Plaintiff's Exhibit 4111
ETH.MESH.12831391-92 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH-08476311 - Cytotoxicity assessment of Ulstem sling
Gynecology Solutions
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]
June, 2009 Klosterhalfen intermediate report on explanted mesh (highlighted)
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
Librojo updated TVT Declaration (10-23-15) [12 pages]
McCabe email re - Sheath Sales Tool - 464
MSDS-Marlex Polypropylenes
P4122 - SEM Figure 183: Sample J7959 13409 (Photographs)
Payments to Medscand [9.16.13 Exhibit T-3192]
Payments to Medscand by J&J [9.16.13 Exhibit T-3183]
Payments to Ulmsten as Consultant [9.16.13 Exhibit T-3204]

**Production Materials**

Published clinical data and RCTs - Ethicon.com - 4204-C
Seven Year Dog Study - T-2263
TVT Abbrevio IFU - 01.2015
TVT Exact IFU - 01.2015
TVT IFU - 01.2015
TVT Patient Brochure - 2015
TVT-O la bandelette trans-obturatrice (Photograph)
TVT-Obturator IFU - 01.2015



**Company Witness Depositions**

<b>Deponent [Date of Deposition]</b>
Hinou, Piet - 04.05.2012 Deposition Testimony
Hinou, Piet - 09.18.2012 Deposition Testimony
Weisberg, Martin - 05.24.2012 Deposition Testimony
Weisberg, Martin - 8.9.2013 Deposition Testimony
Weisberg, Martin - 11.12.2015 Deposition Testimony
Weisberg, Martin - 11.13.2015 Deposition Testimony
Nager, Charles - 06.10.2014 Deposition Testimony

**Other Materials**

<b>Publically Available</b>
24 Hour Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].
FDA - Device Labeling Guidance #G91-1 March 1991
FDA Considerations about Surgical Mesh for SUI [03.27.2013].
FDA Executive Summary: Surgical mesh for treatment of women with POP and SUI [09.08.2011]
FDA News Release: Surgical Placement of mesh to repair pelvic organ prolapse poses risk [07.13.2011].
FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surigical Mesh in Repair of POP and SUI. Issued: 10.20.2008.
FDA Questions: Reclassification of the Urogynecologic Surgical Mesh Instrumentation.
Device Labeling Guidance
Deposition Subject Matter-Design and Development of Mesh Products
Oxford Levels of Evidence; <a href="http://www.cebi.ox.ac.uk/fileadmin/_processed_/csm_Evidence_pyramid_bluef5c85529a0.jpg">www.cebi.ox.ac.uk/fileadmin/_processed_/csm_Evidence_pyramid_bluef5c85529a0.jpg</a>
AUA Guideline for the Surgical Management of Female Stress Urinary Incontinence Update (2009)
ACOG, AUGS Practice Bulletin Summary of 155 (replaces 63 from 2005) Urinary Incontinence in Women. November 2015.
AUGS SUFU Position Statement on MUS for SUI
AUGS SUFU Frequently Asked Questions by Patients MUS for SUI
AUGS SUFU Frequently Asked Questions by Providers MUS for SUI
AUGS Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders
AUA (2011) - Position Statement on the Use of Vaginal Mesh for SUI
FDA Considerations about Surgical Mesh for SUI
IUGA Position Statement on MUS for SUI (2014)
IUGA Mid-urethral sling (MUS) procedures for stress incontinence (2011)
2013 Sept. NICE 171 Guideline - The management of urinary incontinence in women
ICS Fact Sheet 2015
RANZOG and UGSA 2014 Position Statement
2012 ABOG - Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
AUA National Medical Student Curriculum Urinary Incontinence
AUGS Resident Learning Objectives
ACGME Program Requirements.

## Betty McCumber - Case Specific

<b>Depositions</b>
McCumber, Betty - 4.11.2017
<b>Expert Reports</b>
<b>Other</b>
<b>Medical Records</b>
Adena Health Systems - Billing 1-7
Adena Medical Group - Billing 1-9
Adena Regional Medical Center - Pathology 1-2
Adena Regional Medical Center - Radiology 1-1
Adena Regional Medical Center - Radiology 2-2
Adena Urology - Billing 1-7
Adena Urology - Billing 8-16
Adena Urology - Medical 1-5
Adena Urology - Medical 17-17 (cert)
Adena Urology - Medical 6-6 (cert)
Adena Urology - Medical 7-16
Baker Joyce LPC - Medical 1-1 NRS
Centers for Medicare & Medicaid - Insurance NR cert or letter 1-1
Centers for Medicare & Medicaid - Insurance NR cert or letter 2-3
Haller Marla D DO - Medical 1-2 NRS
Holzer Clinic - Medical 1080-1101
Holzer Clinic - Medical 1-256
Holzer Clinic - Medical 251-515
Holzer Clinic - Medical 516-1079
Holzer Medical - Billing 10-14
Holzer Medical - Billing 1-9
Holzer Medical Center - Billing 15-16
Holzer Medical Center - Medical 137-191
Holzer Medical Center - Medical 1-93
Holzer Medical Center - Medical 94-136
Holzer Medical Center - Medical cert 192-192
Holzer Medical Center - Pathology 1-1 NRS
Holzer Medical Center - Radiology 1-24
Holzer Medical Center - Radiology 25-27
Kincaid Stephen Craig Dr - Medical 1-134
Kings Daughters Family Care - Medical 1-31
Kings Daughters Family Care - Medical 132-132
Kings Daughters Family Care - Medical 133-719

**Betty McCumber - Case Specific**

Kings Daughters Family Care - Medical 32-90
Kings Daughters Family Care - Medical 720-769
Kings Daughters Family Care - Medical 770-844
Kings Daughters Family Care - Medical 91-131
Kings Daughters Family Care Centers - Billing 845-874
Nooranissa J Pasha MD - Medical 1-1 NRS
Ohio Health Heart And Vascular Physicians - Medical 1-1
Ohio Health Physician Group - Billing 1-1
Plaintiff Profile Form 1-5
Plaintiff Profile Form 6-10
Plaintiff Supplied Records - 198-294
Plaintiff Supplied Records 100-197
Plaintiff Supplied Records 1-1
Plaintiff Supplied Records 2-99
Shriver Family Practice - Medical 1-17
Shriver Family Practice - Medical 18-18 CER
Shriver Family Practice - Medical 19-19 CER
Southern Ohio Medical Center - Billing 1-1 NRS
Southern Ohio Medical Center - Medical NR cert or letter 1-1
Southern Ohio Medical Center - Pathology 1-1 NRS
Southern Ohio Medical Center - Radiology 1-1
SSA Retirement and Disability - 1-290
SSA Retirement and Disability - 291-592